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JUL 31 2000

510(k) SUMMARY
Safety and Effectiveness Summary

Pathway CTS 2000 Pelvic Floor Training System

Submitted by:

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Contact Person:

Richard Horton

Date Submitted:
May 12, 2000

NAME OF DEVICE

Trade name: Pathway CTS 2000 Pelvic Floor Training System
Common name: Non-implanted Electrical Continence Device
Classification name: 78 KPI, ClassII, (876.5320)

IDENTIFICATION OF PREDICATE DEVICE

-The device to which we claim substantial equivalence is the Hollister InCare PRS pelvic floor therapy system K961872 manufactured by Hollister, Inc.

DESCRIPTION OF DEVICE

The Pathway CTS 2000 is used to monitor OR stimulate the pelvic floor muscles for the treatment of incontinence. The perineometer sensor is connected to the Pathway CTS 2000 to provide Bio-feedback to the patient. This allows the patient to monitor their pelvic muscle activity which is otherwise difficult due to the anatomical location of the pelvic floor muscles. The perineometer sensor is connected to the Pathway CTS 2000 device to provide stimulation to the patient. This assists the patient with muscle contractions.

The Pathway CTS 2000 uses Pathway Perineometer Sensors which are single-user sensors. The patient inserts the sensor into the vagina or rectum and uses the Pathway CTS 2000 to monitor the muscle activity during contraction and relaxation of the pelvic floor muscles. The patient can also use the Pathway CTS 2000 to electrically stimulate the pelvic floor muscles to assist the contraction. The aim is to improve the strength and control of the pelvic floor muscles.

INTENDED USE

Indications For Use:

- **Urinary Incontinence : Stress, Urge and Mixed Incontinence**
- **Neuromuscular Reeducation**
- **Fecal Incontinence (EMG Use Only)**

SUMMARY OF TECHNICAL CHARACTERISTIC COMPARISON TO PREDICATE DEVICE

	Pathway CTS 2000	**InCare PRS K961872**
Intended Use	Treatment of Urinary Incontinence	Treatment of Urinary Incontinence
Stimulator Output	0-100 mA	0-30 V
Waveform	Asymmetrical Balanced Pulsed Current	Square, Symmetrical, Balanced, Biphasic
Charge/pulse at 500 ohms	28uC	60uC
Frequency	12.5, 50 Hz	12.5, 20, 50, 100 Hz
Peak pulse intensity	100 mA	30V
Pulse width	.3 ms fixed	.3 ms, 1 ms
Ramps	2 sec on ramp, one sec off ramp	On ramp: 20%, 40%, 60%, 80%, 100% of "On" time, no off ramp
Duty Cycle	On (sec): 1-80 Off (sec): 0-80	On (sec): 1-80 Off (sec): 0-80
Session Duration (min)	0-30	0-30
Programmable features	None by Patient; Frequency, Duty cycle, Session length by physician	None by patient; Pulse width, Frequency, Duty cycle, Session Length by physician
Vaginal EMG/Stim Probe Used	Pathway Vaginal EMG/Stimulation Sensor K993976	InCare Vaginal EMG/Stim Probe K891773
Anal EMG/Stim Probe Used	Pathway Anal EMG/Stimulation Sensor K993976	InCare Anal EMG/Stim Probe K930530
Vaginal EMG/Stim probe electrode surface area:	2.31 cm^2	7.98 cm^2
Anal EMG/Stim probe electrode surface area:	2.12 cm^2	1.99 cm^2
Power Density (full output @ 500 ohms)	Pathway Vaginal EMG/Stim Sensor: .032 W/cm^2 Pathway Anal EMG/Stim Sensor: .035 W/cm^2 (maximum intensity, .3ms pulse width, 50Hz)	Probe 9595 - .047 W/cm^2 Probe 9596 - .239 W/cm^2 (maximum intensity, 1ms pulse width, 100Hz)
EMG Ranges	0-5, 0-30, 0-100, 0-1000 uV Ranges	0-5, 0-10, 0-25, 0-100, 0-250, 0-500 uV Ranges
EMG Bandwidth	20-500Hz	100-500 Hz
EMG Signal Processing	Root Mean Square (RMS)	Root Mean Square (RMS)
EMG Detection	Bipolar	Bipolar
Vaginal Pressure Probe Used	Pathway Vaginal Pressure Sensor manufactured by DesChutes Medical K934552.	InCare Vaginal Pressure Probe K891774
Anal Pressure Probe Used	Pathway Anal Pressure Sensor manufactured by DesChutes Medical K934552.	InCare Anal Pressure Probe K891774
Work Period (sec)	1-80 seconds	1-80 seconds
Rest Period (sec)	0-80 seconds	0-80 seconds
Session Duration (min)	1-60 minutes	1-60 minutes

NON-CLINICAL PERFORMANCE DATA

A series of bench tests were performed using the Pathway CTS 2000 to show the device accurately measures EMG and Pressure signals and applies stimulation and is substantially equivalent to the predicate device. The Pathway CTS 2000 was used to measure a known input signal and the measured value was compared to the known input signal to check the accuracy of the measurement.

The bench tests show the Pathway CTS 2000 accurately measures EMG signals, Pressure signals, and applies stimulation.

CLINICAL PERFORMANCE DATA

The Pathway CTS 2000 was used in a series of simple clinical tests to show the device accurately measured EMG signals, Pressure signals, and provided stimulation and to show they were equivalent to the predicate device. A test subject was instructed to perform a series of contractions and relaxations using the Pathway CTS 2000 and also the predicate device. The resulting contractions were monitored using a pressure perineometer sensor in the alternate placement (vagina or rectum) to compare the performance of the sensors.

The clinical tests show the Pathway CTS 2000 accurately monitors and provides stimulation to the pelvic floor muscles. The clinical tests also show the Pathway CTS 2000 performs similarly to the predicate device

BIOCOMPATIBILITY TESTING

The Pathway Vaginal EMG/Stimulation Perineometer Sensor, the Pathway Anal EMG/Stimulation Perineometer Sensor, The Pathway Vaginal Pressure Perineometer Sensor, and the Pathway Anal Pressure Perineometer Sensor have been laboratory tested for the safety of the materials. The Pathway Perineometer Sensors were found to be safe under the standards required for each test.

CONCLUSION

The Pathway CTS 2000 is safe and effective for its intended use. The Pathway CTS 2000 is substantially equivalent to the predicate device.

END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2000

Mr. Richard Horton
The Prometheus Group
2 Mallards Cove
Duxbury, MA 02332

Re: K001515
Pathway CTS 2000 Pelvic Floor Training System
Dated: May 12, 2000
Received: May 16, 2000
Regulatory Class: II
21 CFR 876.5320/Procode: 78 KPI

Dear Mr. Horton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION 2 - STATEMENT OF INDICATIONS FOR USE

2.1 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____
Device Name: Pathway CTS 2000 pelvic floor training system

Indications for Use:

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* **Urinary Incontinence : Stress, Urge and Mixed Incontinence**
* **Neuromuscular Reeducation**
* Fecal Incontinence (EMG Use Only)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001515

Prescription Use: X OR Over-the-Counter Use: _____
(Per 21 CFR 801.109)